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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,531	02/25/2005	Mitsuru Kuribayashi	MUR-046-USA-P	7067

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EXAMINER
DICKINSON, PAUL W

ART UNIT	PAPER NUMBER
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,531	KURIBAYASHI ET AL.	
	Examiner	Art Unit	
	PAUL DICKINSON	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/9/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I in the reply filed on 10/27/2009 is acknowledged.

Claim Objections

Claim 3 is objected to because of the following informalities: In the equation "(B + C)/A ≥ 1.5% by weight", variables A, B, and C appear to have the unit "% by weight". Dividing a % by a % (i.e. (% +%)/%) gives a unit-less number (the % in the numerator cancels the % in the denominator). Therefore this equation should be rewritten as "(B + C)/A ≥ 1.5" and "% by weight" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if A, B, and C are weights or % by weight. The claim states "wherein the composition (weight) of the mixture of the ionic synthetic polymer(s) (A), the nonionic synthetic polymer(s) (B), and the naturally-occurring polymer(s) (C)..." which implies that A, B, and C are weights. The claim continues "... is such that (B + C)/A ≥ 1.5% by weight and/or A + B + C ≥ 7% by weight. The "% by weight" on the right side of "A + B + C ≥ 7% by weight" implies that A, B, and C are % by weight. The "% by weight" on the right side of "(B + C)/A ≥ 1.5% by weight" implies

that A, B, and C have the units "% by weight", although even this is somewhat unclear because if A, B, and C all have the same units, then the "1.5" should be unit-less (see ***Claim Objections***). For these reasons it is unclear what the units of A, B, and C are.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1133985 (EP '985; document already in record). EP '985 discloses an adhesive gel for iontophoretic formulations (see abstract). The adhesive gel may comprise an acidic polymer such as polyacrylic acid (an ionic synthetic polymer), a nonionic synthetic polymer, gelatin (a naturally-occurring polymer), a polyhydric alcohol such as glycerin, a polyfunctional epoxy compound (a crosslinking agent), and a drug (see paragraphs 19-28). This satisfies instant claims 1, 4-5, and 7-10. Several disclosed nonionic synthetic polymers may be incorporated into the gel, including polyvinylpyrrolidone and polyvinyl alcohol as binders (see paragraph 24), and polyethylene glycol as one of the one or more polyhydric alcohols (see paragraph 26). This satisfies instant claim 6. Further regarding instant claim 4, polyacrylic acid has anionic functional groups in the monomer unit ($CH_2CH_2COO^-$) which satisfies this claim. Further regarding instant claim 10, the phrase "can be delivered from the cathode side of the iontophoretic formulations" is being interpreted as an intended use limitation. The recitation of an intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the adhesive gel of EP '985 meets all the structural limitations of the claimed adhesive gel and it would therefore be fully capable of being delivered from the cathode side. The gel can be adjusted to a pH of between 3 to 7 (see paragraph 22), which satisfies instant claim 13.

EP '985 fails to disclose a specific example comprising an acidic polymer such as polyacrylic acid (an ionic synthetic polymer), a nonionic synthetic polymer, gelatin (a naturally-occurring polymer), a polyhydric alcohol such as glycerin, a polyfunctional epoxy compound (a crosslinking agent), and a drug.

It would have been obvious to one of ordinary skill in the art to prepare an adhesive gel comprising an acidic polymer such as polyacrylic acid (an ionic synthetic polymer), a nonionic synthetic polymer, gelatin (a naturally-occurring polymer), a polyhydric alcohol such as glycerin, a polyfunctional epoxy compound (a crosslinking agent), and a drug, as this is one means taught by EP '985 of affording an adhesive gel that allows a basic drug to be delivered effectively into an *in vivo* site via iontophoresis. It would have been further obvious to optimize the amount of the ionic synthetic polymer (A), nonionic synthetic polymer (B), and naturally-occurring polymer (C) in the gel to achieve a pH of between 3 to 7 and improved efficacy of the drug. In this way, one would find the amounts disclosed in instant claims 2-3 through routine experimentation. EP '985 provides sufficient guidance to this end. EP '985 teaches that the polyacrylic acid (A) is added to adjust the pH and may be present from 1 to 20% by weight (see paragraph 23). EP '985 further teaches that polyethylene glycol (B) may be present in 10 to 60% by weight (see paragraph 26). EP '985 further teaches that the gelatin (C) (the naturally-occurring polymer) may be present from 0.1 to 15% by weight (see paragraph 28). These ranges fully overlap with Applicant's ranges in instant claim 2. These ranges also fully satisfy the equations $(B + C)/A \geq 1.5$ and $A + B + C \geq 7\%$ in instant claim 3. If the maximum of each of these ranges is taken, then $(B + C)/A = (60 +$

15)/(20) = 3.8 ≥ 1.5 and A + B + C = 20 + 60 + 15 = 95% ≥ 7%. "'[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.' In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955)" MPEP § 2144.05, II.

Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1133985 (EP '985) in view of Nowicki (Nowicki, Effects of iontophoretic versus injection administration of dexamethasone, Medicine & Science in Sports & Exercise, 34(8), 2002, 1294-1301). The relevant portions of EP '985 are given above. In addition, EP '985 teaches adding anti-inflammatory agents as the drug (see paragraphs 29 and 35). EP '985 fails to disclose, however, a drug listed in instant claim 12, such as dexamethasone sodium phosphate (a water-soluble steroid hormone).

Nowicki teaches administration of corticosteroids, such as dexamethasone sodium phosphate, for the treatment of inflammation (see page 1294, entire page). Administration of these compounds by iontophoresis is noninvasive, atraumatic, and painless, which offers advantages over traditional injection of the same agents (see page 1294, entire page; page 1301, Conclusions section).

It would have been obvious to incorporate dexamethasone sodium phosphate as the anti-inflammatory agent of EP '985 to treat inflammation. The art recognizes that dexamethasone sodium phosphate is preferably administered by iontophoresis owing to the noninvasive, atraumatic, and painless nature of iontophoretic delivery. The adhesive gel of EP '985 offers a high efficacy means for delivering the anti-inflammatory

to the patient via iontophoresis. It would therefore be obvious to deliver dexamethasone sodium phosphate using the adhesive gel of EP '985.

Claims 1-10 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 1133985 (EP '985) in view of US 5682726 ('726). The relevant portions of EP '985 are given above. In addition, one preferred drug of EP '985 is ephinephrine (see paragraph 44; examples). EP '985 fails to disclose an adhesive gel wherein oxygen dissolved in the gel is positively removed by placement with nitrogen and/or vacuum kneading at the time the ingredients are added and kneaded.

'726 teaches that oxygen levels in iontophoresis compositions may be reduced by a number of techniques, including replacing oxygen with an inert gas such as nitrogen and/or incorporating an oxygen scavenger such as sodium metalsulphite (see col 3, lines 19-44; col 5, lines 1-11). The purpose of removing oxygen is to increase the stability and shelf life of the drug (see abstract). This technique is particularly suited for iontophoretic compositions containing epinephrine (see col 4, lines 19-22).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to remove oxygen from the adhesive gel of EP '985 by one of the techniques disclosed by '726. The art recognizes that removing the oxygen will result in a product with a longer shelf life. This would be especially important in the embodiment of EP '985 wherein ephinephrine is the drug, as '726 suggests such oxygen removal is particularly desirable for increasing the shelf life of iontophoretic compositions comprising ephinephrine. The oxygen removal techniques taught by '726

are not identical to the removal techniques in instant claim 14, the latter encompassing positively removing the oxygen by replacement with nitrogen and/or vacuum kneading at the time the ingredients are added and kneaded. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). See MPEP § 2113. In the instant case, the same product will be made (i.e. an adhesive gel with decreased levels of oxygen) whether the oxygen is removed by the steps of '726 or the steps of instant claim 14. In other words, Applicant's adhesive gel which is deoxygenated by the method steps of instant claim 14 is indistinguishable from the adhesive gel of EP '985 which is deoxygenated according to the techniques of '726. For this reason, the product of instant claim 14 is patentably indistinct from the product rendered obvious by EP '985 in view of '726.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL DICKINSON whose telephone number is (571)270-3499. The examiner can normally be reached on Mon-Thurs 9:00am-6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Primary Examiner, Art Unit 1618

Paul Dickinson
Examiner
AU 1618

January 12, 2010